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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,733	02/27/2001	Petra Loos	02481.1726	9899

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EXAMINER
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SIEFKE, SAMUEL P

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/763,733

Applicant(s)

LOOS, PETRA

Examiner

Samuel P Siefke

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

In view of the Appeal Brief filed on 4/21/04, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is applied as set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 13-16 are rejected because they do not further limit claim 8, they all rely on a limitation that is already claimed in the independent claim. Further claims 13-16 do not add structural limitation to claim 8.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "the material to be tested" which does not further limit the apparatus in claim 8.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **8-13,15,17-,19 and 21-24** are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta et al. (USPN 4,856,909).

Mehta discloses a pharmacological dissolution apparatus that comprises:

- a mesh basket configured to receive a material to be tested (fig 2,4, ref. 18; col. 4, lines 65-27);
- a lid (fig. 4, ref. 40) including a handle (fig. 2, ref. 12) on one side of the lid;
- the lid (40) includes at least one fixing clip (fig 6, ref. 30) on a side of the lid opposite the handle (looking at fig 6, the top of the handle is where ref. 60 is and the on the opposite side of the top of the handle are the clips);
- the basket is cylindrical in shape and includes an open end and a closed end (fig 2,4, ref. 18; col. 4, lines 65-27);

Art Unit: 1743

- the basket includes a narrow metal band around at least an open end of the basket (fig. 6, ref. 26 or 27, col. 4, lines 66-67);
- the handle includes a bracket configured to allow removal of the device from the testing apparatus (the handle is the bracket; as discussed in specification of the current application on page 5, lines 32-34);
- the device is configured to fit within a paddle agitator, rotating basket apparatus (col. 1, line 48- col.2, line 41);
- the material to be tested is medicament in solid form (col. 1, line 6- col.2, line 41);
- the lid is a plate (fig. 4, ref. 40);
- the fixing clip is configured to connect the lid to the basket (fig. 6 and fig 2);
- the lid includes three fixing clips (fig 5, ref. 30, 30 and 30);
- the handle includes a rod (fig. 2, ref. 14, or the rod can be handle 12);
- the mesh forming the basket is a wire screen fabric (fig 2,4, ref. 18; col. 4, lines 65-27).

Claims **14** and **16** are rejected under 35 U.S.C. 102(b) as being anticipated by Bischoff et al. (USPN 3,802,272).

Bischoff discloses an automatic dissolution rate determinator for determining dissolution rates of pharmaceutical tablets. The apparatus includes a plurality of mesh baskets, which are positioned in a container that is connected to a continuous flow cell (col. 1, lines 45-67; col. 4, lines 7-25). The mesh baskets have closed lids that are

Art Unit: 1743

connected to a spindle (handle) so the basket can be raised and lowered in and out of the medium (col. 4, lines 6-26).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim **18** and **20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (USPN 4,856,909) in view of GB 2136123.

Mehta discloses a wire mesh basket discussed above.

Mehta does not teach the lid of the basket be made of mesh.

GB '123 teaches a dissolution testing machine that comprises a mesh container for a test a solid pellet, a perforated plastic cap 31 is positioned on top of the mesh container. It would have been obvious to one having an ordinary skill in the art to

Art Unit: 1743

modify Mehta to have a lid that is perforated in order to maximize fluid flowing through the basket and be made out of mesh to still retain structural integrity.

### ***Response to Arguments***

Applicant's arguments filed 8/11/03 have been fully considered but they are not persuasive. Applicant's argument "Mehta et al. does not disclose or suggest use of a handle." The chuck 40 is connected to a drive shaft 12 (col. 4, lines 43-55), which can be used to carry the connected mesh basket. Handle, defined by Webster Dictionary, is a part that is designed especially to be grasped by the hand. Handle, defined by Webster's Encyclopedic Unabridged Dictionary of the English Language (definition 2) is, that which may be held, seized, grasped, or taken advantage of in effecting a purpose. Shaft 12 is in a cylindrical form that would be able to be grasped by a hand, therefore being structurally capable of performing the function of a handle. Applicant argues, "the outer shaft 12 is rotating during use, it follows that it is not "designed especially" to be grasped by the hand as it would rotate in the holder's grasp, and therefore, it cannot be grasped by a hand." When the shaft is not rotating "sample not be analyzed" the shaft would not be rotating. Therefore one would be able to use it as a handle, as argued above. Applicant argues "Mehta is completely silent as to the use of a handle on the lid of its apparatus, and the figures do not disclose or suggest the use of a handle." The drive shaft 12 "handle" is structurally attached on top of the lid. Therefore it is on the lid.

Art Unit: 1743

Applicant argues "the Examiner is incorrect in his assertion that the basket of Mehta may be used with a paddle agitator, continuous flow cell, and rotating basket apparatus." Claim 8 recites the testing apparatus being at least one of a paddle agitator, a continuous flow cell, and a rotating basket apparatus. Mehta discloses a paddle agitator is disclosed on col. 4, lines 55-61 and a rotating basket apparatus. This is the primary use of Mehta, a basket that rotates in a solvent.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

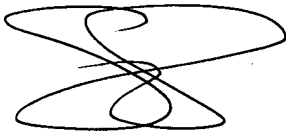
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.




Art Unit: 1743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke

A handwritten signature in black ink, consisting of a large, stylized 'S' that loops around itself.

February 4, 2005

A handwritten signature in black ink, appearing to read 'Jill Warden' in a cursive style.

Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700